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EXAMINER

LAMBERTSON, DAVID A

| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,059

Applicant(s)

GELLISSEN ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
4a) Of the above claim(s) 20-33 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-19, 34 and 35 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed January 19, 2005.

Amendments were made to the claims.

Claims 1-35 are pending in the instant application. Claims 20-33 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1-19, 34 and 35 are under consideration in the instant application. Any rejection of record in the previous Office Action, mailed July 27, 2004, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Objections

Claims 4-6 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, claims 4-6 are directed to nucleic acids having 80%, 90% and 95% homology to a nucleic acid represented in claim 1 (a). Claim 1 (a) concerns a sequence having the DNA sequence set forth in SEQ ID NO: 1. Because dependent claims 4-6 increase the scope of claim 1(a) by encompassing other sequences besides the DNA sequence set forth in SEQ ID NO: 1, the claims fail to further limit the independent claim.

Claim 1(e) is objected to for failing to further limit claim 1(a). Claim 1(a) is directed to a nucleic acid "having" the sequence set forth in SEQ ID NO: 1; the term "having" is "open-type"

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language, and is thus synonymous with “comprising” language. Thus, claim 1(e) merely “comprises” a nucleic acid “comprising” SEQ ID NO: 1; since claim 1(a) is already directed to this, claim 1(e) fails to further limit claim 1(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for the reasons set forth in the previous Office Action, with the exception that claim 19, which was not treated on the merits due to its comprising an improper multiple dependency, is now included in the rejection.**

Response to Arguments Concerning Claim Rejections - 35 USC § 112

Applicant's arguments filed January 19, 2004 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal:

1. Applicant argues that the instant claims satisfy the Written Description requirement because the claimed polynucleotides exhibit the common feature that, when they are expressed in a cell, produce a polypeptide having chorismate synthase activity (see for example page 13, bottom of

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the first full paragraph of Applicant's response). Applicant asserts that this recitation of functional language would demonstrate to the skilled artisan that they were in possession of the claimed invention (see for example page 14, second and third paragraphs of Applicant's response).

2. Applicant argues that, while not necessarily agreeing with the Office's position concerning the Written Description requirement, the claims have been amended to remove all claim language referring to non-specific homologs, fragments and variants of SEQ ID NO: 1 (see for example page 13, second full paragraph of Applicant's response).

Applicant's arguments have been fully considered but are not found convincing for the following reasons:

1. The Written Description requirement for a claimed genus requires either (a) the description of a representative number of species by actual reduction to practice or (b) the disclosure of relevant identifying characteristics of the genus coupled with either a known or disclosed correlation between function and structure. In the instant case, the claims simply recite a function without a correlation between that function and the structures (i.e., the relevant identifying characteristics) required to perform the function. In other words, while the skilled artisan would understand that the claimed polynucleotide must encode a polypeptide with chorismate synthase activity (i.e., its function), the skilled artisan cannot envision what polynucleotides besides SEQ ID NO: 1 (i.e., what structures) will necessarily have this function. This is because the instant specification does not teach either a representative number of polynucleotides having chorismate synthase activity or a structure-function relationship for SEQ

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ID NO: 1 such that the skilled artisan would know which portions of SEQ ID NO: 1 are required to encode a polypeptide having chorismate synthase activity. The Written Description cannot be satisfied by reciting a function (e.g., encoding a polypeptide with chorismate synthase activity), and then claiming any polynucleotide sequence having that function without a clear indication as to what specific features of the polynucleotide are required for that function.

2. The assertion that the amendments to the claims have removed all reference to non-specific homologs, fragments and variants of SEQ ID NO: 1 does not appear to be correct. Specifically, claims 1 (b-d and f) continue to read on non-specific homologs, fragments and variants of SEQ ID NO: 1. Thus, the Written description as set forth previously continues to apply to the instant claims.

Claim 1 is directed to nucleic acids encoding polypeptides with chorismate synthase activity, wherein the nucleic acids comprise a nucleic acid selected from one of sections (a) through (f) of claim 1. Claim 1(b) is directed to nucleic acids which hybridize to a complementary strand of SEQ ID NO: 1, and claims 1(c, d and f) refer back to, and thus encompass, claim 1(b). Claim 1(b) has no size, degree of complementarity or hybridization conditions as it relates to the nucleic acid sequence that must hybridize to the complementary strand of SEQ ID NO: 1. Thus, in the broadest reasonable interpretation of claim 1(b), the nucleic acid can be as small as three nucleotides long; i.e., a sequence that encodes for a single amino acid. Thus, the broadest reasonable interpretation of the claim includes nucleic acids encoding polypeptides having chorismate synthase activity, wherein the nucleic acid comprises only a single amino acid in common with the polypeptide encoded by SEQ ID NO: 1. The same can be stated for claims 1(c, d and f). Thus, as set forth in the previous Written Description

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requirement, the claims continue to read on variants, non-specific homologs and fragments of SEQ ID NO: 1. As such, the amendment is not sufficient to overcome the previous Written Description rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 7-9, 11, 12, 14, 15 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Gray (as recited in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action, with the exception that claim 19, which was not treated on the merits due to its comprising an improper multiple dependency, is now included in the rejection.**

Claims 1, 2, 7-9, 11, 12, 14, 15 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Eberhard (as recited in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action, with the exception that claim 19, which was not treated on the merits due to its comprising an improper multiple dependency, is now included in the rejection.**

Response to Arguments Concerning Claim Rejections - 35 USC § 102

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Applicant's arguments filed January 19, 2004 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal:

Applicant suggests the art rejections are based essentially on the grounds of the Written Description rejection (see for example page 17, bottom paragraph). Based on said grounds, Applicant asserts that the amendment of the claims adequately traverses the Written Description rejection, and thus overcomes the application of both the Gray and Eberhard as prior art (see for example page 18, second full paragraph).

Applicant's arguments have been fully considered but are not found convincing for the following reasons:

It is reiterated that the assertion that the amendments to the claims have removed all reference to non-specific homologs, fragments and variants of SEQ ID NO: 1 does not appear to be correct. Specifically, claims 1 (b-d and f) continue to read on non-specific homologs, fragments and variants of SEQ ID NO: 1. Thus, the Written description as set forth previously continues to apply to the instant claims.

Claim 1 is directed to nucleic acids encoding polypeptides with chorismate synthase activity, wherein the nucleic acids comprise a nucleic acid selected from one of sections (a) through (f) of claim 1. Claim 1(b) is directed to nucleic acids which hybridize to a complementary strand of SEQ ID NO: 1, and claims 1(c, d and f) refer back to, and thus encompass, claim 1(b). Claim 1(b) has no size or degree of complementarity as it relates to the nucleic acid sequence that must hybridize to the complementary strand of SEQ ID NO: 1. Thus, in the broadest reasonable interpretation of claim 1(b), the nucleic acid can be as small as three nucleotides long; i.e., a sequence that encodes for a single amino acid. Thus, the broadest

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reasonable interpretation of the claim includes nucleic acids encoding polypeptides having chorismate synthase activity, wherein the nucleic acid comprises only a single amino acid in common with the polypeptide encoded by SEQ ID NO: 1. The same can be stated for claims 1(c, d and f). Thus, as set forth in the previous Written Description requirement, the claims continue to read on variants, non-specific homologs and fragments of SEQ ID NO: 1. As such, the amendment is not sufficient to overcome the previous Written Description rejection.

As both Eberhard and Gray teach polypeptides having at least one amino acid in common with the polypeptide encoded by SEQ ID NO: 1 and will hybridize to SEQ ID NO: 1 under some conditions (absent evidence to the contrary, Eberhard and Gray continue to teach the sequences as claimed, which still read on non-specific homologs, fragments and variants of SEQ ID NO: 1. As a result, the rejections are still maintained in view of Applicant's arguments.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636



JAMES KETTER
PRIMARY EXAMINER